UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,740	12/11/2003	Chung Shih	00482-T8954.NP.CIP	9514

20551 7590 09/06/2007
THORPE NORTH & WESTERN, LLP.
8180 SOUTH 700 EAST, SUITE 350
SANDY, UT 84070

EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	
MAIL DATE	**DELIVERY MODE**
09/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,740	SHIH ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of response to restriction requirement and request for extension of time filed 07/09/07. Claims 1-43 are pending.

Priority

The examiner acknowledges this application as a continuation-in-part of application serial number 09/971,074 filed 10/03/2001, claiming benefit of provisional application number 60/279,363 filed March 27, 2001.

Election/Restrictions

Applicant elected Group I with traverse and further requested reconsideration of the restriction requirement. Upon further consideration and review of the claims of examined application and the parent case, the requirement is withdrawn and claims 1-43 are hereby examined.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rathi et al. (US 6,004,573).

Rathi discloses a water-soluble biodegradable ABA-type block copolymer drug delivery system having a gelation temperature at or below the body temperature (abstract, column 4, lines 57-65 and column 5, line 5), that is at body temperature the formulation is liquid and flowable

meeting the limitation that the polymer solution is flowable at body temperature. Specifically Table 1 describes the behavior of the PLGA-PEG-PLGA tri-block polymer to gel above the gelation temperature. Rathi discloses an average molecular weight ranging between from about 3,100 and about 4,500 for the block copolymer (abstract; Table 1; claims 1, 5, 12, 18) meeting the molecular weight requirements of claims 1, 4, 8, 12, 18, 23, 29, 34 and 39; the block copolymer having about 51-83% by weight of hydrophobic A polymer block and about 17-49% by weight of hydrophilic B polymer block (abstract; column 5, lines 6-8) meeting claims 1, 4, 8, 12, 18, 23, 29, 34 and 39; the A block polymer consists of poly (lactide-co-glycolide) and the B block consists of polyethylene glycol (PEG) or polyethylene oxide (PEO) or polyoxyethylene; the lactate or lactide content of the A block is between about 65 and 85 mole percent and the glycolate or glycolide content in the A block is between about 15 and 35 mole percent (column 5, lines 4-16) meeting claims 3, 6, 11, 17, 20, 32, 37 and 42. The A polymer block of Rathi is made from lactide and glycolide monomers (example 1), which meets the scope of claims 1, 2, 5, 10, 12, 16, 17, 18, 19, 23, 25, 29, 31, 34, 36, 39 and 41. "Free flowing liquid at body temperatures" recited in claims 1, 4, 8, 12, 18, 23, 29, 34 and 39 is the property of the formulation/composition. "Capable of solubilizing" as recited in the claims is the intended use of the composition. Claims 5, 10, 16 are product by process claims. Rathi teaches the method of claims 18 and 23 by providing the biodegradable polymer and parenterally administering the formulation the formulation (abstract, column 4, lines 63-65; column 5, lines 21-23). The method of claims 34 and 39 is the preparation of the polymer formulation and Rathi as described above and in Examples 6, 7 and 80

Rathi made the observation that ABA-type block copolymers that have hydrophobic A block copolymer content of between about 51-83% by weight and ABA block copolymer having a molecular weight of between about 3,100 and 4,500 are soluble in water at low temperatures and undergo reversible thermal gelation at mammalian physiological body temperatures (column 6, lines 32-40). Rathi specifically discloses that the ABA-type block polymer composition gels at body temperature, which is 37 °C (abstract and column 1, lines 19-21) and this means that between 35 °C and 36.999 °C, the ABA-type polymeric composition of Rathi is a liquid. Rathi discloses that the concentration of the soluble block copolymer at below the gelation temperature is the functional concentration which ranges from 3% to 50% (column 9, lines 55-65) and the concentration of the block copolymer is related to the sol-gel phase transition of the polymer as a function of temperature (column 9, lines 63-67 and Figure 1).

The biodegradable drug delivery system of Rathi is an aqueous solution of the ABA block copolymer and dissolved drug or drug as a suspension or emulsion, the drug delivery system is administered parenterally, topically, transdermally or inserted into ocular, vaginal, rectal, nasal, oral and transurethral cavities; the drug makes up between 0.01 to 20% by weight of the of the drug delivery formulation (column 10, lines 19-65 and claims 12-18) and parenteral means intramuscular, intraperitoneal, intra-abdominal, subcutaneous, intravenous and intra-arterial (column 5, lines 22-24). Rathi specifically teaches a method of administering a drug to a warm blooded animal in a liquid form below the gelation temperature (claim 1) and in Rathi the gelation temperature is the physiological temperature of the warm blooded animal, which is 37 °C (abstract), since the instant method of claims 18 and 23 administer instant composition to

warm blooded animals, the method of Rathi meets the scope of the instant method claims 18 and 23.

Rathi specifically teaches that the block copolymer increases solubility and chemical stability of many drugs (column 10, line 66 to column 11, line 28) and polyols including sugars, amino acids, surfactants, polymers, proteins and certain salts can be incorporated into the block copolymer as additives (column 12, lines 4-11) and amino acids and certain salts can be buffer. Thus the composition of Rathi comprises excipients meeting the scope of instant claim 13.

The instant invention is directed to block copolymeric composition comprising block copolymeric carrier and a drug with the proviso that when the copolymer is an aqueous solution, the copolymeric composition is a liquid at temperatures at body temperatures. The instant polymeric composition encompasses the polymeric composition of Rathi in light of the discussion following.

The functional concentration of the biodegradable copolymer in instant claims 9, 14, 24, 30, 35 and 40 is between 1-50%. In Rathi, the functional concentration of the biodegradable copolymer is from about 3% to about 50%, which lies within the instant range of 1-50% and because Rathi's functional concentration is a narrower range or species of the instant range, Rathi's functional concentration meets the scope of the instant functional concentration range. The lactide or lactic acid content of the A block ranges from 20 to 100 mole percent and the glycolide or glycolic acid ranges from 0 to 80 mole percent in instant claims 3, 6, 11, 17, 20 and 26. The lactate or lactide content is between about 65 to 85 mole percent and glycolate or glycolide content is between 15 and 35 mole percent in the A block in Rathi and these ranges lie within the instant ranges. Thus Rathi's ranges in the content of lactate or lactide and glycolate

or glycolide meet the scope of the instant ranges. The method of administering in the prior art meets the scope of the administration method of instant claims 18, 22, 23 and 28. Regarding claims 7, 15, 21 and 27, the instant drug content of 10^{-6} to 100% encompasses the narrower drug content range of 0.01 to 20% or the preferred range of 0.01% to 10% disclosed in Rathi, and Rathi meets the scope of the instant drug content.

Rathi in column 12, line 66 to column 13 line 10 exemplifies a specific ABA block copolymer that comprises 75% by weight hydrophobic A block of PLGA and 25% by weight hydrophilic B block of PEG, ABA block copolymer that has an average molecular weight of 4000, 75% mole percent lactate or lactide and 25 mole percent glycolate or glycolide. Although Rathi teaches the preparation of the above specific PLGA-PEG-PLGA tri-block copolymer, Rathi broadly discloses block copolymer having about 51-83% by weight of hydrophobic A polymer block and about 17-49% by weight hydrophilic B polymer block.

Since the hydrophobic A polymer block in Rathi ranges from 51-83% and the hydrophilic B polymer block ranges from 17-49% and since these ranges are covered in the ranges of the instant A and B block, there are points within those ranges where the percent amounts of the A and B blocks of the instant claims and the prior art are the same. This is true also for the mole percent of the lactide and glycolide, for the molecular weight of the block copolymer and for the drug content in the polymeric composition. Thus, at those points when they are the same the polymeric compositions of the prior art and the invention are the same and thus the properties would be the same. Thus, the polymeric compositions of the invention and the prior art would have the same property. Specifically, the gelation properties of both composition would be the same and there is nothing in the instant claims that indicates that the properties are not. It

appears that there is an aspect of applicants' invention that allows the composition to remain liquid at above body temperature and applicants have not communicated that in the claims. Thus Rathi anticipates the scope of the instant claims. In the alternative, since the claimed composition and the method (claims 18, 23, 29, 34 and 39 read on the composition and the methods of Rathi, it flows that the properties of flowable liquid at body temperature would be inherent to both the claimed and prior art disclosed so that it would be obvious that same compositions would exhibit same properties. In the absence of factual evidence, the properties of the claimed composition being flowable at body temperature would not render the claimed invention over a prior art product that is the same as that which is claimed.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-79, 1-69 and 1-77 of U.S. Patent Nos. 6592899, 6117941 and 6201072 respectively.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated, or would have been obvious, over the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the prior issued patents use and make the same formulation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on Monday-Friday from 7:30 am to 3:30 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600